

## Food and Drug Administration, HHS

## § 880.5680

distribution of body pressure. The device is used to prevent and treat decubitus ulcers (bed sores).

(b) *Classification*. Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 880.9.

[45 FR 69682, Oct. 21, 1980, as amended at 63 FR 59229, Nov. 3, 1998]

### § 880.5560 Temperature regulated water mattress.

(a) *Identification*. A temperature regulated water mattress is a device intended for medical purposes that consists of a mattress of suitable size, filled with water which can be heated or in some cases cooled. The device includes electrical heating and water circulating components, and an optional cooling component. The temperature control may be manual or automatic.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9.

[45 FR 69682, Oct. 21, 1980, as amended at 61 FR 1123, Jan. 16, 1996; 66 FR 38804, July 25, 2001]

### § 880.5570 Hypodermic single lumen needle.

(a) *Identification*. A hypodermic single lumen needle is a device intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin. The device consists of a metal tube that is sharpened at one end and at the other end joined to a female connector (hub) designed to mate with a male connector (nozzle) of a piston syringe or an intravascular administration set.

(b) *Classification*. Class II (performance standards).

### § 880.5580 Acupuncture needle.

(a) *Identification*. An acupuncture needle is a device intended to pierce the skin in the practice of acupuncture. The device consists of a solid, stainless steel needle. The device may have a handle attached to the needle to facilitate the delivery of acupuncture treatment.

(b) *Classification*. Class II (special controls). Acupuncture needles must

comply with the following special controls:

(1) Labeling for single use only and conformance to the requirements for prescription devices set out in 21 CFR 801.109,

(2) Device material biocompatibility, and

(3) Device sterility.

[61 FR 64617, Dec. 6, 1996]

### § 880.5630 Nipple shield.

(a) *Identification*. A nipple shield is a device consisting of a cover used to protect the nipple of a nursing woman. This generic device does not include nursing pads intended solely to protect the clothing of a nursing woman from milk.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9.

[45 FR 69682, Oct. 21, 1980, as amended at 59 FR 63011, Dec. 7, 1994; 66 FR 33804, July 25, 2001]

### § 880.5640 Lamb feeding nipple.

(a) *Identification*. A lamb feeding nipple is a device intended for use as a feeding nipple for infants with oral or facial abnormalities.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. If the device is not labeled or otherwise represented as sterile, it is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[45 FR 69682, Oct. 21, 1980, as amended at 66 FR 38804, July 25, 2001]

### § 880.5680 Pediatric position holder.

(a) *Identification*. A pediatric position holder is a device used to hold an infant or a child in a desired position for therapeutic or diagnostic purposes, e.g., in a crib under a radiant warmer, or to restrain a child while an